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EXAMINER

CHANG, ROSIE YUH LOO

ART UNIT	PAPER NUMBER
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1762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/817,393	Applicant(s) KERRIGAN, CAMERON	
	Examiner ROSIE YL CHANG	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 2/21/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed on 2/21/2007 is acknowledged. In the response, applicant amended claims 1-10 and 14-16, cancelled claim 17. Claims 1-16 are being considered in this Office action.

Response to Arguments

1. Applicant's arguments filed on 2/21/2007 with respect to claims 1, 5-7 and 14-16 have been considered but are moot in view of the new ground(s) of rejection.
2. Applicant's arguments, filed on 2/21/2007, with respect to claims 2-4, 6-10, 11-13, 17 have been fully considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1, 5-7 and 14-16 under 35 U.S.C. § 102(b) as being anticipated by Taylor et al. (US 6,214,115) has been withdrawn, as necessitated by Applicant's amendment, in favor of the revised rejections below.

(1)

Claims 1, 3, 5, 11, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Banas et al. (US 5,628,786).

Banas et al. ('786) teach a method of coating a stent comprising inserting a stent over a mandrel (Figures 6 and 7; col. 10, line 44 to col. 11 line 5) having a hollow tubular body and pores disposed on a surface of the mandrel, the pores extending through the body; applying a coating composition to the stent; and applying a vacuumed pressure to the hollow tubular body for extracting some of the coating composition (col. 11, line 12-55) that is applied to the stent, wherein the pressure is applied during (col. 11, line 12-18) application of the coating composition to the stent. Additionally, Banas et al. ('786) teach (Fig. 3 and col. 8, line 39-42) rotating the stent about the longitudinal axis of the stent during the application of the coating composition to the stent. Thus Banas et al. ('786) disclose all of the limitations of claims 1, 3 and claim 11, and anticipate the claimed invention.

As for claims 5 and 12:

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Banas et al. ('786) teach (col. 10, line 60-63) the outer surface of the mandrel contacts the inner surface of the stent.

(2)

Claims 1, 4, 5-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Parsons et al. (US 6,521,284,).

Parsons et al. ('284) teach a method of coating stent (col. 9, line 13) comprising inserting a stent over a mandrel (Figures 1,2, and 6; col. 4, line 34 to col. 5, line 20) having a hollow tubular body and pores disposed on a surface of the mandrel, the pores extending through the body; applying a coating composition to the stent; and applying (col.7, line 34-49) a vacuumed pressure to the hollow tubular body for extracting some of the coating composition that is applied to the stent, wherein the pressure is applied during application of the coating composition to the stent. Thus Parsons et al. ('284) disclose all of the limitation of claim 1, and anticipate the claimed invention.

As for claim 4:

Parsons et al. ('284) teach (col. 3, line 51 to col. 4, line 3) the coating composition includes a polymer dissolved in a solvent and a therapeutic substance optionally added thereto.

As for claims 5 -10:

Parsons et al. ('284) teach (col. 4, line 57-67) the mandrel includes a spacer (4a), i.e. a support element, to contact a first end of the stent, another spacer (4b), i.e. a lock element, to contact a second end of the stent, the hollow tubular body connecting the support element to the lock element. Parsons et al. ('284) further teach (col. 5, line 21-

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22) two spacers (4a) and (4b) being used to maintain said stent above the outer surface of said mandrel, therefore, the inner surface of the stent does not make contact with outer surface of the mandrel. In another example, Parsons et al. ('284) teach (col. 5, line 30-31) that if said stent is placed directly on the outer surface of said mandrel, the spacers are not required. Additionally, Parsons et al. ('284) teach (see Fig. 5 and 6) support element penetrates at least partially into the first end of the stent and/or wherein the lock element penetrates at least partially into the second end of the stent, and support and/or lock element include a bore in fluid communication with the hollow tubular body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant's arguments, filed on 2/21/2007, with respect to claims 2-4, 6, 7-10, 11-13 have been fully considered. With respect to the Villareal et al. (US 6,605,154) reference, in light of the Statement of Common Ownership, the Villareal et al. ('154) reference is removed, and therefore the rejections of claims 2-4, 6, 7-10, 11-13 under 35 U.S.C. § 103 (a) have been withdrawn. However, upon further consideration, a new ground(s) of rejections are made below.

(3)

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Banas et al. ('786).

Banas et al. ('786) teach that which is disclosed above.

Banas et al. ('786) teach (Fig. 3 and col. 8, line 35-51) a method of coating a stent, which is mounted on a rotatable mandrel having a hollow tubular body and pores extending through the body and a vacuum device in fluid communication with the mandrel. Banas et al. ('786) teach the coating composition is applied by dipping the stent into a coating solution tank. In regard to the requirement of spraying the coating composition onto the stent, it was well known in the art to interchange spraying and dipping as methods of applying a coating solution onto a stent. Therefore, one of ordinary skill in the art would have found it obvious to spray the coating composition onto the stent to form a coating, with the expectation of the same or similar results as that of dipping.

(4)

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (of record) in view of Sundar (US 7,105,198).

Taylor et al. ('115) teach a method of dip-coating a stent (col. 1, line 24) by inserting a stent over a mandrel having a hollow tubular body and pores on the body, which is in communication with a pressure device to receive a pressure (col. 1, line 27-28; 42-45). The stent is also affixed on the mandrel by two collars (col. 2, line 49-62). Taylor et al. ('115) teach dipping the mandrel with the stent to a coating solution tank

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and then withdrawing the coated stent from the coating solution in a controlled rate, applying a vacuum pressure into the hollow body to modify the coating substance that applied to the stent, wherein the application of the pressure is conducted subsequent (col. 2, line 63 to col. 3 line 4) to the termination of the application of the coating substance. Taylor et al. ('115) fail to teach rotating the stent about the longitudinal axis of the stent during coating process.

Sundar ('198) teaches a method of coating a stent (abstract) including immersing the stent which is mounted (see Fig. 4; col. 5, line 25) on a mandrel into a coating liquid, and withdrawing the immersed portion of the stent from the coating liquid. The stent is simultaneously rotated with respect to the coating liquid while the stent is being immersed and withdrawn. Sundar ('198) further teaches (col. 6, line 66 to col. 7, line 1) the rate of rotation during withdrawal may influence the uniformity of the coating and rate of withdrawing may control the coating thickness on the stent (col. 7, line 7-8). Sundar ('198) would have reasonably suggested rotating the stent about the longitudinal axis of the stent during immersion and withdrawal in dip-coating process. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the dip-coating process of Taylor et al. ('115) by incorporating the rotation of stent about the longitudinal axis of the stent as suggested by Sundar ('198) with the expectation of successful results, because Sundar ('198) teaches (col. 7, line 38-43) the concurrent spinning and dipping of the stent speed the rate at which the coating is applied. In addition, the teaching of Sundar ('198) provides efficient utilization of coating solution and reduced the cost of manufacturing of coated stent.

As for claim 15:

Sundar ('198) teaches (Fig. 4; col. 5, line 24-25) the stent is slidably mounted on a cylindrically shaped mandrel 170. Therefore, the inner surface of the stent is in contact with the outer surface of the mandrel.

As for claim 16:

Taylor et al. ('115) teach (col. 3, line 17-23) an alternative mandrel design for coating a stent by applying a plastic sheath having spiral slots formed around its outer surface, which (Fig 2 and Fig 3) is placed around the external periphery of said mandrel. Therefore, the inner surface of the said stent does not make direct contact with an outer surface of the said mandrel.

(5)

Claims 2, 11, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Parsons et al. ('284) in view of Zhong et al. (US 6,676,987).

Parsons et al. ('287) teach that which is disclosed above.

Parsons et al. ('284) teach a method of coating a stent in a controlled process (col. 2, line 10-24) by applying pressure to the coating composition on the stent surface. The stent of Parsons (284) is mounted on a mandrel, which has a hollow body and pores on the surface (col. 5, line 14-15), the said mandrel being in communication with a pressure device receiving pressure (col. 5, line 5-7) to modify the coating substance that being applied to said stent. The pressure is applied at least during application of the

coating composition to the stent. However, Parsons et al. ('284) fail to teach rotating the stent while applying a coating composition thereto.

Zhong et al. ('987) teach a method of coating a stent in a controlled condition (col. 2, line 43-51). The stent of Zhong ('987) is mounted (col. 3, line 45-60) on a support 35, i.e. a mandrel. Zhong et al. ('987) further teach in order to expose different sides of the stent to the coating nozzle; the stent is rotated by the mandrel along stent longitudinal axis during the coating process.

Parsons et al. ('284) and Zhong ('987) both concern the uniformity of the coating on the stent. Zhong ('987) would have reasonably suggested rotating the stent about the longitudinal axis of the stent during a spraying (col. 7, line 32-35) coating process. It would have been obvious to one of ordinary skill in the art to modify the coating method of Parsons et al. ('284) by rotating stent on the mandrel of Parsons et al. ('284) with the expectation of successful results, because Zhong ('987) teaches a successful method to expose the entire exterior surface of the stent to the spraying nozzle (see Fig. 7) which is located in a fix site either above or below the stent. Therefore, the combined coating method of Parsons et al. ('284) and Zhong would have a uniformed coating applying on all sides of the stent.

As for claim 13:

Parsons et al. ('284) teach (col. 5, line 21-22) the inner surface of the stent does not make contact with the outer surface of the mandrel.

Allowable Subject Matter

There is no allowable subject matter at this time.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSIE YL CHANG whose telephone number is 571-272-6466. The examiner can normally be reached on **MONDAY TO FRIDAY 7: 00AM TO 3:30 PM**.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIMOTHY MEEKS can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


KEITH HENDRICKS
PRIMARY EXAMINER